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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/994,980	11/27/2001	John E. Carlson	2748 CON	2946

7590 05/14/2004

United States Surgical, a division of
TYCO HEALTHCARE GROUP LP
150 Glover Avenue
Norwalk, CT 06856

EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/994,980	CARLSON ET AL.	
	Examiner	Art Unit	
	Michael Thaler	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/27/01, 8/20/02</u> | 6) <input type="checkbox"/> Other: _____ |

The disclosure is objected to because of the following informalities: On page 7, line 15, "34" and "distal" are incorrect. On page 7, line 16, "36" is incorrect. On page 8, line 23, "Fig. 3A" is incorrect. On page 8, line 30, after "dilator", "14" should be 30. On page 9, line 1, "3" is incorrect. Appropriate correction is required.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the locking structure defined in claims 23 and 37 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claims 16-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. (5,201,756) in view of Makower et al. (5,380,290). As to claim 16, Horzewski et al. disclose the steps of positioning a radially expandable sleeve (e.g. 90 in figures 5A and 5B) over a guidewire and expanding the sleeve (col. 11, line 58 to col. 12, line 8). Horzewski et al. fail to disclose the step of forming a percutaneous tissue tract to the target vessel. However, Makower et al. teach that

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such a tissue tract should be formed (by needle 14) prior to the introduction of a guidewire therethrough apparently in order to obtain the advantage of facilitating the introduction of the guidewire. It would have been obvious to form a percutaneous tissue tract to the target vessel in the Horzewski et al. procedure so that it too would have this advantage. As to claim 20, for example, Horzewski et al. fail to disclose the expandable sleeve comprising a tubular braid. However, it is old and well known in this art to construct expandable sleeves as tubular braids so that they expand smoothly. It would have been obvious to so construct the Horzewski et al. expandable sleeve so that it too would have this advantage. As to claims 26-29 and 40-43, Horzewski et al. fail to disclose the claimed dimensions. However, it would have been obvious to so dimension the Horzewski et al. as claimed in order to fit within a blood vessel. As to claim 30, Horzewski et al. disclose the step of introducing a dilator 150 over the guidewire (in conjunction with the expandable sleeve 90) and through the expandable sleeve 90 (when the dilator 150 is inserted into the sleeve 90 prior to insertion into the body) to increase the diameter of the expandable sleeve (when the dilator is retracted). As to claim 33, Horzewski et al. fail to disclose using an outer tube of the dilator to remain in place after the dilator is removed to

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maintain the large diameter of the sleeve. However, it is old and well known in this art to so construct dilators (as admitted by applicant on page 5, lines 32-33) so that the main portion of the dilator can be removed leaving the outer tube or sheath in place. It would have been obvious to so construct the Horzewski et al. dilator so that it too would have this advantage.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. (5,201,756) in view of Makower et al. (5,380,290) as applied to claim 16 above, and further in view of Shockey et al. (4,994,033). Horzewski et al. disclose the steps of introducing a radially expandable sleeve over a guidewire (in the embodiment of figures 1A to 2F noting col. 9, lines 13-16) prior to the introduction of a dilator (the diagnostic or therapeutic device described in col. 9, lines 21-22) and introducing the dilator to enlarge the sleeve and tissue tract (formed in view of Makower et al. as set forth above). Horzewski et al. fail to disclose the step of introducing the dilator over the guidewire (since the guidewire is removed as described in col. 9, lines 19-22). However, it is old and well known to introduce a diagnostic or therapeutic device over a guidewire and through a guide catheter so that the device may still be guided even after it emerges from the guide catheter. For example, Shockey et al. teach this step in col. 3, lines 56-

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66. It would have been obvious to keep the guidewire in place during the introduction of the Horzewski et al. diagnostic or therapeutic device so that it too would have this advantage.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
5/11/04



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731